INTRALUMINAL STENT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. Patent Application Serial No. 09/623,347, filed November 15, 2000, which is a U.S. national phase application from International Patent Application PCT/US99/04694, international filing date March 4, 1999, which claims priority based on U.S. Provisional Application Serial No. 60/076,946, filed March 5, 1998, which is hereby incorporated by reference.

FIELD OF INVENTION

[0002] This invention relates generally to intraluminal prostheses, and more particularly to intraluminal stents comprised of zig-zag or sinusoidal wire hoops.

BACKGROUND OF THE INVENTION

[0003] A common method of treating vessel diseases such as stenoses, strictures, thrombosis, or aneurysms involves placing a stent into the affected vessel. Among other advantages, stents prevent vessels from collapsing, reinforce vessel walls, increase cross sectional area (and thereby volumetric flow), and restore or maintain healthy blood flow. Many stents have been developed, and the prior art includes a wide variety of types and methods for their manufacture.

SUMMARY OF THE INVENTION

[0004] The present invention is a generally cylindrical intraluminal stent including a plurality of circumferential wire hoops disposed in succession along the axis of the stent. Each of the hoops has zig-zag or sinusoidal members defined by a successive series of struts connected by apex sections alternately pointing in opposite axial directions. The struts may be substantially straight sections connected to essentially sharp apex sections in a jagged zig-zag configuration, or the apex sections may be more rounded so that together with the struts there is formed a sinusoidal configuration. The lengths of these struts may be uniform throughout the stent or may vary alternately or continuously. Likewise, the angles or radii of curvature and configurations of the apices may be uniform or may vary. To provide mechanical integrity, selected portions of the hoops may be secured against relative axial movement, such as by spot welding overlying straight sections either in an individual hoop or in adjacent hoops. Such connections may also be made with bridging members aligned with straight sections in adjacent hoops.

[0005] These connections (with or without intervening bridging members) may be disposed in one or more linear or helical paths along the length of the stent, thus acting as stabilizing spines. Alternatively, these connections may be disposed in other preselected patterns, such as alternating around the circumference of the stent, to impart stability at these preselected locations.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] The figures provided are for illustrative purposes, and are not drawn to scale. The expanded relative dimensions allow a better understanding of the present invention. One skilled in the art will readily determine actual dimensions based on information supplied in this specification.

[0007] FIG. 1 is a diagrammatic view of an exemplary embodiment of a stent according to this invention, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened; also shown are mandrel pins used in forming the stent.

[0008] FIG. 2 is a diagrammatic view of another exemplary embodiment of a stent according to this invention having multiple spines and axial and circumferential offsets between facing apex sections, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened; also shown are mandrel pins used in forming the stent.

[0009] FIG. 3 is a partial diagrammatic view of another exemplary embodiment of a stent according to this invention having a plurality of longitudinal sections, the middle section having a different number of spines, a different number of zigs, and a different zig length than the end sections, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened.

[0010] FIG. 4 is a diagrammatic view of another exemplary embodiment of a stent according to this invention having end portions with different zig characteristics relative to a center portion, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened; also shown are mandrel pins used in forming the stent.

[0011] FIG. 5 is a diagrammatic view of another exemplary embodiment of a stent according to this invention having connecting members that include separate bridging members, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened; also shown are mandrel pins and weld holes used in forming the stent.

[0012] FIGS. 6A is a diagrammatic view of an exemplary embodiment of a stent according to this invention having interdigitated zigs, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened.

[0013] FIGS. 6B - 6D are diagrammatic views of enlarged portions of the stent of FIG. 6A, showing an exemplary end weld, and exemplary middle weld, and an exemplary radiopaque marker, respectively.

[0014] FIG. 6E is a diagrammatic view of an exemplary embodiment of stent 6A, where the stent is shown in its normal tubular configuration.

[0015] FIG. 6F is a diagrammatic view of an exemplary embodiment of a stent according to this invention having interdigitated zigs and a plurality of longitudinal sections of different zig configurations, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened

[0016] FIG. 7 is a partial side view of an exemplary embodiment of a stent according to this invention having alternating zig lengths, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened.

[0017] FIG. 8 is a partial diagrammatic view of another exemplary embodiment of a stent according to this invention having straight-edged apex sections, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened.

[0018] FIG. 9 is a partial diagrammatic view of another exemplary embodiment of a stent according to this invention having connecting members formed by elongated struts, where the tubular stent is shown opened along a line parallel to the stent axis, and flattened; also shown are mandrel pins used in forming the stent.

[0019] FIG. 10 is a partial diagrammatic view of the stent shown in FIG. 6A mounted on a mandrel during fabrication of the stent.

DETAILED DESCRIPTION OF THE INVENTION

[0020] FIG. 1 illustrates an exemplary stent **10** according to the present invention. Stent **10** is generally cylindrical and adapted to be inserted into a lumen. Stent **10** has been cut longitudinally and laid flat for purposes of illustration. Stent **10** is formed by winding a continuous filament such as a wire **11** into a zig-zag or sinusoidal configuration and into a plurality of circumferential hoop members **12a**, **12b**, **12c** disposed in succession along the axis of stent **10**. Wire **11** is preferably nitinol wire, which provides a stent that auto-expands by shape memory, but it may be made of any suitable material, including stainless steel and thermoplastic polymers. Thus, the stent may be capable of deployment by shape memory auto-expansion,

thermal auto-expansion or balloon expansion, as are well-known in the art. The width of the wire affects the radial force exerted by stent **10**. Increasing the diameter of wire **11** increases the radial force.

[0021] For convenience, the configuration of the wire is referred to throughout having a "zig-zag" shape with zigs or zig lengths. As so used herein, however, the term "zig-zag" encompasses not only a jagged zig-zag shape where the apex sections are relatively sharp and the struts are substantially straight, but also a sinusoidal shape where the apex sections are rounded and, together with the struts, form a shape resembling a sine wave having an amplitude (zig length) and a period or wavelength (zig width). Similarly, although the apex sections may be referred to as defining a zig angle, the angle may be more rounded such that lesser and greater angles may be more envisioned as smaller and larger radii of curvature, respectively. Of course, the actual wire configuration may have a shape intermediate the jagged zig-zag and rounded sine wave shapes, or may be even more rounded than a sine wave, and the apex sections may in fact have a truncated, straight edge rather than a rounded shape or sharp angle, as described herein later.

[0022] To form stent **10**, wire **11** is wound around pins **13** on a mandrel (not shown). The mandrel is typically cylindrical (although other shapes may be used as necessary to form stents of varying shapes) and of a diameter determined by the diameter of the vessel into which stent **10** is to be inserted. Typically, the mandrel diameter, and hence the intended diameter of stent **10**, is slightly larger (for example, by one millimeter) than the diameter of the vessel. The length of stent **10** is also determined by the particular application.

[0023] Stent **10** is formed by winding wire **11** around pins **13** beginning at point **A** in FIG. 1. Wire **11** is extended to and around pins **13a, 13b, 13c** and so forth. In this manner, zig-zag members are formed and defined by a successive series of substantially straight sections (struts) **14** connected by apex sections **15** alternately pointing in opposite axial directions. The winding continues in this manner around the mandrel until a first hoop member **12a** is completed by winding wire **11** once around the circumference of the mandrel. Hoop member **12a** as shown in FIG. 1 has a circumference lying in a plane substantially perpendicular to the axis of the mandrel (and hence of stent **10**). Once a first hoop member **12a** is formed, wire **11** is extended from pin **13d** to and around pin **13e**. Winding then continues as before to form a second hoop member **12b** adjacent to first hoop member **12a**. By forming hoop members in this manner, adjacent hoops **12a** and **12b** are connected by the portion of wire **11** extending between first hoop member **12a** and second hoop member **12b**. At

the completion of the second hoop member **12b**, wire **11** is again extended to the third hoop member **12c**, which is wound as before, and so forth until the desired number N of hoop members **12** are formed along the length of stent **10**. Thus, as shown in FIG. 1, the winding extends in a series of hoops between hoops **12a** and hoop **12N**, with the wire beginning at point **A** and ending at point **B**. After completion of winding, wire **11** is typically cut so that the wire terminates short of points **A** and **B**, generally terminating within the first hoop **12a** and last hoop **12N**, respectively, as described with reference to FIG. 6C herein later.

[0024] Stent **10** is removed from the mandrel and pins **13a**, **13b**, **13c**, etc., prior to use. In the illustrated embodiment, each hoop member **12** has one pair of aligned, adjacent struts **14a** and **14b**. According to one embodiment of the present invention, aligned, adjacent struts **14a** and **14b** of the same hoop are welded together. Such welding may be spot welding along the length of aligned, adjacent struts **14a** and **14b**, or it may be a continuous weld. In either case, a welded, connective spine **16** is formed along the perimeter of stent **10**. Connective spine **16** typically winds around the circumference of stent **10** in an offset helical fashion (the embodiment shown flat in FIG. 1 being cylindrical or tubular in actual use). Connective spine **16** provides strength and stability to stent **10** while preserving the flexibility of stent **10**. During insertion of stent **10** into a vessel (described below), connective spine **16** renders stent **10** easier to push through a catheter. As an alternative to welding, connective spine **16** may be formed by connecting aligned, adjacent struts **14a** and **14b** according to any other suitable attachment means, including without limitation, tying, suturing, gluing, and stapling, with the glue or sutures being absorbable or non-absorbable, and including the use of polymer-containing connections.

[0025] When stent **10** comprises thermally expandable nitinol, stent **10** is annealed before removal from the mandrel and pins **13a**, **13b**, **13c**, etc., at an annealing temperature for about one hour and then allowed to cool. This annealing temperature is desirably on the order of about 500°C, although any temperature sufficient to effect annealment of stent **10** will suffice. During annealing, it may be necessary to secure the nitinol wire to the mandrel by wrapping bailing wire, a thicker gauge and different material than the nitinol, around the stent on the mandrel. Such annealing of nitinol wire imparts a memory to the nitinol, such that stent **10** will "remember" its annealed shape and return to it after subsequent reconfiguration. This is a known property of nitinol, which has two distinct temperature-dependent phases, martensite and austenite. Below a certain temperature (the martensite transition temperature), nitinol is martensitic; above a certain temperature (the austenite

transition temperature), it is austenitic. It is in the austenitic phase that nitinol remembers its annealed configuration.

[0026] After annealing, stent **10** is removed from the mandrel on which it is wound to compress stent 10 into a configuration for introduction to a body passageway. Then, it is cooled to below its martensitic transition temperature. In this phase, nitinol is malleable and has virtually no resiliency. Thus, it can be easily compressed. Stent **10** can be easily returned to its annealed shape by heating it to a temperature above its austenite transition temperature. Above this temperature, the stent resumes its annealed configuration.

[0027] In its annealed configuration, stent **10** has a first diameter. This is a relatively large diameter that is the intended final diameter of stent **10**. In order to be inserted into a body vessel, stent **10** must be compressed such that it may be inserted into a catheter. As indicated above, with a nitinol stent, this is accomplished by cooling stent **10** to below its martensite transition temperature at which temperature stent **10** is malleable and less resilient. Stent **10** can then be easily compressed into a second, relatively small diameter for insertion into the catheter. Once inside the catheter, stent **10** may be advanced to the desired location within a body vessel according to methods known in the art and discharged from the catheter at that location. U.S. Patents Nos. 5,405,377 and 5,609,627, the disclosures of which are incorporated herein by reference, contain additional details regarding the formation, use, and insertion of nitinol stents. Those patents are incorporated herein by reference for their teaching on those subjects. When stainless steel, thermoplastic polymers, or other materials are used for wire **11**, formation, use and insertion of stent **10** may be accomplished according to methods known to those skilled in the art.

[0028] Connective spine **16** lends strength, including hoop strength, to stent **10** during and after implantation to better resist compressive forces within the vessel in which stent **10** is implanted. Connective spine **16** also allows flexibility, however, such that stent **10** may be easily compressed and expanded during the insertion process.

[0029] Particular features of the stent according to this embodiment of the invention are illustrated in FIG. 2. As shown in FIG. 2, facing apex sections **15** of respective adjacent hoops of stent **10A** are offset circumferentially from one another by a distance **D1**, as opposed to abutting one another. The offset allows stent **10A** to be compressed to a smaller diameter (profile) for insertion into the catheter because the apex sections do not contact one another and hinder such compression. Increasing the axial distance **D2** between apex sections **15** (the "zig gap") also prevents

interference between these sections during compression. The particular amount of offset and zig gap can be optimized according to particular stent sizes and the desired flexibility and compressed diameter as will be understood by those skilled in the art.

[0030] FIG. 2 also illustrates an embodiment of this invention having multiple, in this case two, connective spines **16**. To form two connective spines **16**, two separate wires **11** and **11A** are used to form stent **10A**. As shown in FIG. 3, first wire **11** is formed in a zig-zag shape extending from point **A** to points **B, C, D, E, F, G, H, I, J, K, L, M, N, O, P** (etc.) sequentially. A second wire **11A** is used to form the remainder of the stent by extending, in sequence from point **E** to points **Q, R, S, A, T, U, V, W, X, Y, Z** (etc.). In this manner, each hoop contains two pairs of aligned, adjacent struts **14a** and **14b**. Aligned, adjacent struts **14a** and **14b** are then welded (or otherwise connected) to form connective spines **16**. In general, the number of wires **11, 11A,** etc. used to form stent **10A** directly corresponds to the number of connective spines **16** that are desired. The strength and rigidity of stent **10A** increase with the addition of connective spines **16**.

[0031] In the above configuration, the mandrel peg at each lettered point may be considered to be one of a set of pegs corresponding to the wire to wound about the set. Thus, pegs at points **A, B, C,** etc. above are a part of one set, and pegs **E, Q, R,** etc. above are part of a second set. Each set, however, contains at least one common peg (for example, **F** in the first set and **W** in the second set) where both wires follow a common path between the common pegs of the circumferentially adjoining sets. The wires that form the common path (adjacent struts **14a** and **14b**) are connected as described above.

[0032] FIG. 3 illustrates another alternative embodiment of this invention wherein the zig length L_1 is varied within stent **10B**. Zig length L_1 is the distance between apex sections **15'** and **15"** measured in a direction parallel to the stent axis (vertical, in FIG. 3). As previously indicated, the zig length may similarly be described as the amplitude of a sinusoidally shaped zig-zag. In this embodiment, the zig length at end sections **22** of stent **10B** may be relatively short (relatively small amplitude), while the zigs in middle section **20** of stent **10B** are relatively long (having greater amplitude). This may provide greater radial force at the ends of stent **10B** to assist in anchoring the stent in place in the vessel into which it is inserted by asserting a greater force against the walls of the vessel. This may also prevent blood from leaking between stent **10B** (when the stent is used in combination with a graft, as will be understood by those skilled in the art) and the vessel wall.

[0033] As illustrated in FIG. 3, there may also be a transition section **21** in which there is a transition zig length, between the short zig length at the stent ends **22** and the long zig length in the stent middle **20**, to provide a gradual transition from the short to the long zigs. Typical short zig lengths are between two and three millimeters. Typical long zig lengths are between three-and-a-half and five millimeters. The actual zig lengths may be optimized for particular applications as will be understood to those skilled in the art based on the disclosure herein.

[0034] Another aspect of this invention involves the variation of the number of zigs in each hoop member. Referring back to FIG. 1, a "zig" is considered to be the part of wire **11** extending from, for example, point **X** to point **Y** to point **Z**. **X-Y-Z** in FIG. 1 is considered to represent one zig. Thus, each similarly-oriented apex section (i.e. each apex section pointing in the same direction) defines a zig. As previously indicated, the number of zigs in a hoop may be similarly described as the number of periods of a sinusoidally shaped zig-zag. In FIG. 1, each hoop member has five zigs. Using fewer zigs allows stent **10** to be compressed to a smaller insertion diameter (that is, fewer zigs decreases the profile of stent **10**). Increasing the number of zigs provides more support for any graft covering used in conjunction with the stent, however, preventing the possibility of in-folding of such graft layer.

[0035] FIG. 4 illustrates an alternative embodiment, not drawn to scale, wherein the center portion **20** of stent **10** has four zigs per hoop member **12**, a first zig length, and one connective spine **16;** and the end portions **22** have six zigs per hoop member **12**, a second zig length, and two connective spines **16**. The second spines on both ends overlap two hoop members **12** of the center portion as a transition. The number of connective spines **16** can thus be varied within a stent to provide a more rigid portion at the ends and a more flexible portion in the middle. The stent illustrated in FIG. 8 may have, for example, a wire diameter of 0.007 inches, a 6.4 mm OD, a 6 mm ID, and a length of 100 mm. Other wire diameters slightly larger than 0.007 inches such as 0.008 or 0.009 inches, for example, will suffice.

[0036] As shown in FIG. 9, another method of making connecting members may comprise axially opposed apex sections **15** of adjacent hoops **12** being axially spaced from one another with one or both of the first and second struts **14'** of the connecting member elongated relative to the remainder of the struts **14** in the adjacent hoops. Such elongated struts **14'** may thus lie adjacent one another for at least some axial distance to permit connection therebetween.

[0037] FIG. 5 illustrates a stent constructed according to another exemplary embodiment of the present invention. Stent **30** is generally cylindrical and adapted to be inserted into a lumen. Stent **30** has been cut longitudinally and laid flat for purposes of illustration. Stent **30** is formed by winding a continuous filament such as a wire **24** into a zig-zag configuration and into a plurality of circumferential hoop members **33, 25a . . . 25N,** and **37** disposed in succession along the axis of stent **30**. Wire **24** is extended to and around pins **23a, 23b, 23c** and so forth. In this manner, zig-zag members are formed and defined by a successive series of substantially straight sections **34** connected by apex sections **35** alternately pointing in opposite axial directions. The winding continues in this manner around the mandrel until a first hoop member **33** is completed by winding wire **24** once around the circumference of the mandrel. Winding then continues as before to form a second hoop member **25a** adjacent to first hoop member **33** and a third hoop member **25b** adjacent to second hoop member **25a**. Unlike hoop members **12** of stent **10** as shown in FIG. 1, hoops **25a . . . 25N** are disposed at an angle to a plane perpendicular to the stent longitudinal axis; wire **24** then gradually spirals about the axis of stent **30** to form a coil. End hoops **33** and **37**, however, are disposed perpendicular to the stent axis. The helical configuration may be effected by each apex section in the helix having one connected strut longer than the other.

[0038] As further illustrated in FIG. 5, adjacent hoops are connected by a separate bridging member **26** adjacent portions of respective straight sections **34** and **34A** of axially opposed apex sections of adjacent hoops. As illustrated in FIG. 5, bridging member **26** is preferably linear and aligned with aligned struts **34** and **34A** of proximate sections of adjacent hoops $\mathbf{25}_i$ and $\mathbf{25}_{i+1}$, although non-linear and non-aligned bridging members are also contemplated in accordance with the present invention, as may be appreciated by those skilled in the art. Separate bridging member **26** may be the same material as or a different material than wire **24** used to form hoops **33, 25a-N,** and **37** of stent **30**, depending on the desired flexibility and compressed stent diameter. In one embodiment, separate bridging member **26** and wire **24** are made of the same material, for example, nitinol. Separate bridging member **26** and wire **24** may have approximately the same or different cross sectional dimensions (i.e. the same or a different wire gauge), depending on the desired implementation.

[0039] An exemplary separate bridging member **26** is preferably formed by extending a wire segment between a pair of pins **28** extending from the mandrel proximate straight sections **34** and **34A** of adjacent hoops $\mathbf{25}_i$ and $\mathbf{25}_{i+1}$. These pins

28 and **29** are in addition to pins **23a, 23b, etc.** used to form zig-zag members of the respective hoops of stent **30**. Wire-segment bridging member **26** is extended between pins **28** and both ends are at least partially wrapped around the pins, preferably with enough tension to remove unwanted slack from the wire, although various amounts of slack may be maintained, depending on the desired rigidity, flexibility, and compressed diameter of stent **30**.

[0040] To effect welds during manufacture of a stent of the present invention, and as shown in FIG. 5, ball weld cutting holes **29** may be formed in the mandrel providing access to the mandrel interior, the holes desirably positioned such that sections to be welded, such as aligned, adjacent struts **34** and **34A**, lie approximately above the ball weld cutting holes. In this way, a laser may be focused into ball weld cutting holes **29** to: (i) remove excess wire extending past ball weld cutting holes **29** and around the pins, and (ii) weld the remaining wire segment between the aligned, adjacent struts of adjacent hoops as, for example, bridging member **26** between struts **34** and **34A.** The connection between bridging member **26** and struts **34** and **34A** may, instead of a weld, may be accomplished according to any other suitable attachment means, including without limitation, tying, suturing, gluing, and stapling, with the glue or sutures being absorbable or non-absorbable, and including the use of polymer-containing connections.

[0041] As further illustrated in FIG. 5, a stent **30** constructed in accordance with the present invention may further include the plurality of separate bridging members **26a-26N** disposed in succession along the length of the stent. Each successive separate bridging member $\mathbf{26}_i$ connects a successive pair of adjacent hoops along the axis of stent **30** to form a spine along the length of stent **30**. The spine may be a continuous spine of helically-aligned bridging members, similar to the spine illustrated in Fig. 1, or may be constructed of a single bridging member connecting a plurality of hoops along the length of the stent. Alternatively, as shown in FIG. 5, each successive connecting member $\mathbf{26}_i$ may be circumferentially offset from a preceding connecting member with respect to the axis of stent **30** to define a helical spine of disjointed connecting members, or a "floating" spine. Hoop members **33, 37** disposed at each end of stent **30** may have the apex sections that point outwardly from the stent disposed in common planes perpendicular to the axis of stent **30,** such as apex sections **35'** of hoop **34** along plane **I**, as shown in FIG. 5.

[0042] To make this transition from hoops other than perpendicular end hoops **33** and **37** to the end hoops, the successive lengths of struts in the end hoops may be reduced along the circumference of the hoops. Additionally, or in the alternative, the

successive amount of interdigitation (overlap) between apex sections of adjacent hoops may increase along the circumference of end hoops **33** and **37** approaching the end of wire **24**.

[0043] FIGS. 6A-6E illustrate stent **40**, another exemplary embodiment of the present invention. In stent **40**, adjacent hoops **42a . . . 42N** are interdigitated with respect to one another. That is, oppositely directed apex sections **44A** and **44B** in respective adjacent hoops **42b** and **42c,** for example, overlap one another axially, or expressed another way, they intersect a common plane angularly disposed with respect to the axis of stent **40**. Hoop members **42a ... 42N** also preferably have zigs substantially in phase circumferentially about stent **40**. Stent **40** comprises a continuous series of similarly-oriented apex sections **44A** arranged in a helix in which each hoop **42*i*** comprises one 360-degree wrap of the helix. Each apex section in the helix comprises two struts attached thereto, in this embodiment with one strut being longer than the other to effect the helical progression. Such a hoop configuration is also seen in U.S. Patent No. 5,575,816 to Rudnick *et al.*, which is incorporated herein by reference and which illustrates a variety of other interdigitated stent configurations.

[0044] In a pair of adjacent hoops, such as hoops **42b** and **42c**, one strut **45** of hoop member **42b** is aligned with and overlaps strut **45** of hoop member **42c**, and is connected to form a connecting member **48a-N**, preferably by spot welding, although other connection mechanisms are contemplated as will be understood by those skilled in the art. Interdigitated stent **40** in its normal tubular form is illustrated in FIG. 6E.

[0045] Referring now to FIG. 10, there is shown a helical stent **110**, corresponding to the layout shown in FIG 6A, on a tubular mandrel **114**. Helical stent **110** or a helical segment thereof, as shown in FIG. 10, may be constructed by winding N filaments **111**, where N is a whole number of at least 1, around N respective sets of pegs **112a-N** on a tubular mandrel **114**. As shown in FIG. 11, N = 1. Each of the N sets includes at least three axially offset pegs, such as pegs **112a**, **112b**, and **112c,** defining a zig-zag configuration at a preselected axial location on mandrel **114**, with circumferentially successive pairs of pegs (pegs **112c** and **112d**, for example) being axially offset in a preselected direction from the pair which precedes it (pegs **112a** and **112b**) so as to form a helical zig-zag pattern repeatedly traversing the mandrel along the length of stent **110**. Each traversal of a preselected angular portion of mandrel **114** by pegs **112a-N** includes at least one common peg (**112r**, for example) approximately 360° helically offset from an adjacent peg (**112k**). The peg adjacent the common peg may be part of the same set of pegs (for instance, where N is equal to 1) or a part of a circumferentially adjoining set of pegs (where N is greater than 1).

Common peg **112r** provides at least one circumferential location in each traversal of a preselected angular portion, where a portion of the filament in each traversal of a preselected angular portion contacts a portion of a filament in an adjacent traversal. This contact may be with the same filament (for instance, where N is equal to 1 as shown in FIG. 11) or with an different filament (where N is greater than 1). A connection **48** is formed along the contacting adjacent filaments or portions thereof, forming a circumferential stent or segment thereof comprised of a helical succession of zig-zags. Thus, the wire configuration may form a helix as shown in FIGS. 6A, 6E, and 11, or a double- or other multiple-helix (not shown). As shown in FIG. 6A, a single filament (N = 1) repeatedly traverses the mandrel (not shown) along a single set of pegs, wherein in each angular traversal of 450° there is a common peg **13'** approximately (in this case slightly greater than) 360° offset from an adjacent peg **13'** (the pegs immediately adjacent each connecting member **48a-N**).

[0046] Stent **40** as shown in FIGS. 6A comprises a plurality of connecting members **48a-N** disposed in succession along the stent axis between pairs of adjacent hoops. Each set of connecting members **48a-N** connects a successive pair of adjacent hoops along the axis of stent **40** to form a spine along the length of the stent. As with the successive connecting members **26** of FIG. 5, each pair of successive connecting members $\mathbf{48}_i$ is circumferentially offset from a preceding connecting member $\mathbf{48}_{i-1}$ with respect to the axis of stent **40**.

[0047] As shown in FIG. 6A, each apex section **44B** includes an apex angle α and a zig width **W** measured between adjacent, apex sections **44A** opposite apex section **44B**. As shown in FIG. 6A, the included angle (zig angle) and zig width of apex sections **44B** are essentially uniform throughout stent **40**, except for the apex sections **44B'** and **44B"** that include the struts **45** that form connecting members **48a-N.** Apex sections **44B'** and **44B"** have a non-uniform zig angle and resulting zig width as compared to apex sections **44B**. As shown in FIG. 6A, the zig including apex section **44B'** has a greater included angle and has a greater zig width than the uniform angle and width included by apex sections **44B**; apex section **44B"** has a lesser included angle and smaller zig width than the uniform angle and width. As shown in FIG. 6A, stent **40** comprises a helical configuration having 4 zigs per 360-degree wrap, each such wrap comprising a hoop. Apex section **44B'** is spaced 5 zigs from each preceding **44B'**; apex section **44B"** is similarly spaced 5 zigs from each preceding **44B"**. Thus, for a stent with N zigs, the non-uniform zigs are spaced every N+1 zigs to achieve the helical pattern of connections **48a-N** as shown in Fig. 6A. In other words, for the 4-zig stent of 6A, connecting members **48a-N** are uniformly distributed in a helical spacing

approximately every 450° along the length of the stent to form a helical spine. Other helical or non-helical spine configurations may be achieved by spacing the non-uniform zigs differently.

[0048] FIGS. 6B and 6C illustrate exemplary spot weld configurations within stent **40**. For adjacent, aligned struts **48b** - $\mathbf{48_{N-1}}$, the portion of each strut adjacent one another may be of a first length having a weld **54** of length $\mathbf{L_1}$, as shown in FIG. 6B. For adjacent, aligned struts **48a** and **48N** on the end hoops, however, the portions of each strut adjacent one another may be longer, and thus may include a weld **56** of length $\mathbf{L_2}$, as shown in FIG. 6B. To avoid sharp edges protruding from the stent, end strut **58** may be cut, as shown in FIG. 6C, so that it terminates a distance **D** from weld **56** in a position that lies short of plane **II** on which apex section **46** lies. For instance, the end of end strut **58** may be cut so that it terminates a distance above plane **II** equivalent to the radius **R** of apex section **46**. As shown in FIG. 6A, end strut **58** has not yet been cut, but may be cut using ball weld cutting hole **29**, similar to those described with reference to FIG. 5.

[0049] FIG. 6D illustrates an exemplary radiopaque marker **59** that may be used with the present invention. Marker **59** may comprise a radiopaque substance, such as a platinum wire, wrapped about a strut on an end hoops. This substance thus defines a surface having a different radiopacity than the area surrounding it. This same effect may be achieved by marking a particular location of the stent with an area of lower radiopacity. One or more markers **59** may be disposed on one or both of the end hoops. Marker **59** generally may be tightly wound with no underlying strut visible to the unaided eye, and may extend 1 - 2 wraps past the start of the radius where the strut bends to form the apex section. Marker **59** is typically configured without sharp edges at the ends.

[0050] FIG. 6F is a diagrammatic view of an exemplary embodiment of stent **60,** opened along a line parallel to the stent axis and flattened, having interdigitated zigs, similar to stent **40** of FIG. 6A-E, but additionally having a plurality of longitudinal sections, similar to stent **10C** as shown in FIG. 4. Middle section **62** has a longer zig length than end sections **64**, and transition sections **63** intermediate the middle section and each end section have a zig length that is between the length of the middle and the end section zigs.

[0051] FIG. 7 illustrates still another stent **70** constructed in accordance with the present invention. Stent **70** has been cut longitudinally and laid flat for purposes of illustration. Stent **70** is formed by winding a wire around pins extending from a

mandrel somewhat similar to the manner described with reference to FIG. 1, although the pins are configured such that zig-zag sections of respective hoops **76a**, **76b**, **76c**, **76d** are of varying height and varying width. In the embodiment illustrated in FIG. 7, the width of the zig length alternates between distance **XX** and **WW** along each hoop circumferentially about stent **70**. The zig length similarly alternates between length **YY** and **ZZ** moving along each hoop circumferentially about stent **70**. Length **ZZ** is approximately half of length **YY** in FIG. 7, although other length variations are contemplated. Adjacent hoops, such as hoops **76a** and **76b,** are phase-shifted by approximately and 180 degrees and inverted with respect to one another. Accordingly, apex sections **65** and **66** of hoop member **76a** pass through a plane perpendicular to the axis of stent **60** determined by the positions of oppositely directed alternate apex sections **67** and **68** in adjacent hoop **76b.** The configuration of FIG. 7 may be incorporated into transition segments of other stents constructed according to the present invention.

[0052] A series of separate bridging members **72a**, **72b**, and **72c** connects adjacent hoops **76a** and **76b**, as shown in Fig. 7. Another series of separate connecting members **74a** and **74b** connects adjacent hoops **62b** and **62c**. Bridging members **72a**, **72b**, and **72c** are angled relative to the tubular axis of stent **70** in opposite orientations than bridging members **74a** and **74b**, to counter rotating effects in stents in which bridging members between successive pairs of adjacent hoops are oriented in the same direction. The number of bridging members may vary, depending on the desired implementation, as may the orientations of bridging members **72a**, **72b**, **72c**, **74a** and **74b**.

[0053] Stent **80** of FIG. 8 is formed by winding a first wire **81** around pins (not shown) on a mandrel. The geometry of the pins may be substantially circular to produce rounded apex sections, as in FIG. 1, or have straight edges such as to produce apex sections having straight edges as in FIG. 8. In this manner, zig-zag members are formed and defined by a successive series of struts **84** connected by apex sections **85** alternately pointing in opposite axial directions. The winding continues in this manner around about half the circumference of stent **80**. A second wire **86** is introduced and wound around the remaining circumference of stent **80** to complete a first hoop member **82a**. Where wires **81** and **86** overlie one another, they may be spot or linearly welded, thus to produce a pair of helical spines lending integrity to stent **80**.

[0054] Any of the variations described herein may be combined with any other variation described herein or known in the art, where practical, to develop a stent architecture according to the present invention. Such variations may be uniformly

utilized throughout the length of the stent, or as shown in Fig. 6F, the stent may comprise a plurality of longitudinal sections, each of which may differ from another segment with respect to, for example without limitation: the size of one or more of the apex section angles, the apex section axial length, the number of apex sections per hoop, the number of connective spines, the spacing or offset between facing apex sections, the type of connecting member, and the uniformity of adjacent zigs. Moreover, the "struts" of each apex section and the connections therebetween may be straight, as in a jagged zig-zag configuration, or curved somewhat, such as when the overall stent section is more sinusoidal.

[0055] Although this invention has been described with reference to particular embodiments, it is not intended that this invention be limited thereto. Rather, the scope of the appended claims should be construed to cover all forms and variants of the invention as may be made by those skilled in the art without departing from the spirit and scope thereof.